

REMARKS

Amendments to the specification

The specification has been amended to add a priority claim to the parent application.

In addition, brief descriptions of several articles listed on page 6 have been added. All of these articles were incorporated by reference in the specification as originally filed (in the second paragraph of page 5), so these descriptions do not constitute new matter.

Furthermore, a typographical error on page 18 has been corrected, by deleting the word "electronic" and replacing it with "electrode". The corrected sentence now indicates that the control unit "... drives electrode devices 100 to apply current. . . ." The Applicant submits that this is consistent with multiple other uses of the phrase "electrode devices 100," and does not constitute new matter.

Amendments to the claims

This application contains claims 1-134, the status of which is as follows:

- (a) Claims 35-39, 41-43, 53-54, and 56-64 have been currently amended.
- (b) Claims 40, 44-52 and 65-70 are as originally filed.
- (c) Claims 1-34, 55, and 71-72 have been canceled without prejudice.
- (d) Claims 73-134 are new.

No new matter has been added. Reconsideration is respectfully requested.

Applicant thanks Examiner Bockelman for the courtesy of a personal interview with Applicant's representative, Sanford T. Colb (Reg. No. 26,856), held in the USPTO on August 10, 2006. At the interview, Mr. Colb argued the patentability of a proposed draft amendment to independent claim 35 under 35 U.S.C. 112, first paragraph, and several new proposed draft independent claims, as described hereinbelow. The Examiner agreed that US Patent 4,608,985 to Crish et al. and US Patent 4,649,936 to Ungar et al. do not teach the application of orthodromic and antidromic stimulation and blocking as proposed in the Applicant's proposed draft claims,

and that the Applicant's proposed draft claims overcome the art as applied in the last office action, provided that US Patent 5,755,750 to Petruska does not teach the invention as recited in the amended claims. The Examiner also agreed that the proposed amendments are acceptable, including their reliance on incorporation by reference, provided that the Applicant clearly indicates the support in the references.

Claims 1-3, 5-18, 21, 26, 30, 32, 33, 35-57, and 60-67 were rejected under 35 U.S.C. 102(b) as being anticipated US Patent 4,608,985 to Crish et al., or, alternatively, US Patent 4,649,936 to Ungar et al. Claims 1-3, 5-18, 21, 26, 30, 32-57, and 60-68 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,628,942 to Sweeney et al. Claims 4, 19-20, 22-25, 27-29, 31, 58, and 69-72 were rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al., Crish et al., or, alternatively, Ungar et al. in view of US Patent 5,755,750 to Petruska et al. Claims 1-34 and 71-72 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of US Patent 6,684,105.

While not necessarily agreeing with these rejections, the Applicant has canceled claims 1-34 and 71-72 without prejudice, in order to expedite issuance of a patent on the subject matter believed to be allowable.

The Applicant has amended claim 35 to recite that the control unit is configured to induce *orthodromic* action potentials. Support for this amendment has already been provided in a response filed August 12, 2003 in the parent application (Application No. 09/944,913). Claim 35 has also been amended to recite that the control unit is configured to induce and suppress the action potentials repeatedly during a series of temporally non-contiguous periods. This amendment recites the elements of claim 55 as originally filed, with changes to conform to the amendment adding "orthodromic," and to clarify antecedent basis. The Applicant has consequently canceled claim 55. (The Applicant notes that the amendment to claim 35 presented herein differs slightly from that presented to the Examiner during the interview with Mr. Colb. Whereas the amendment presented during the interview recited the suppression of antidromic action potentials, the currently-presented amendment recites the suppression of action potentials traveling in the opposite direction of the induced orthodromic action potentials. The Applicant

does not believe this difference has any bearing on the conceptual agreement reached with the Examiner during the interview.)

The Applicant respectfully submits that intermittent inducing of unidirectional orthodromic action potentials, as now recited in claim 35, is novel and unobvious over Crish et al., Ungar et al., and Sweeney et al. In the collision blocking, antidromic techniques described by these references, the signal is applied generally constantly, in order to block substantially all orthodromic pain signals. Indeed, the application of intermittent stimulation for pain collision blocking would be suboptimal, because it would allow some pain signals to reach the brain. Claim 35, as amended, thus recites a substantive difference in apparatus compared to the prior art, which could not be achieved by taking a known collision blocking apparatus and simply turning it around. As mentioned above, during the interview with Mr. Colb, the Examiner agreed that the amendments distinguished claim 35 over Crish et al. and Ungar et al. The Applicant thus submits that claim 35 is now in a condition for allowance. Claims 36-54, 56-70, and 73-86 directly or indirectly depend from claim 35, and are thus also allowable, being of narrower scope than the allowable independent claim from which they depend.

Claims 36-39, 41-43, 53-54, and 56-64 have been amended to provide proper antecedent basis in light of the amendments to claim 35, and/or to make clarifications to the claim language. No new matter has been added.

Claims 73-80, 81, and 82-86 are new, and depend from claims 69, 37, and 35, respectively. These claims are supported in the specification as filed at least as shown in the following table. The Applicant notes that information that is incorporated by reference should be treated as part of the text of the application as filed. MPEP 2163.07(b) states in this regard:

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See >37 CFR 1.57 and < MPEP § 608.01(p) for Office policy regarding incorporation by reference. See MPEP § 2181 for the impact of incorporation by reference on the determination of

whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.

As mentioned above, during the interview with Mr. Colb, the Examiner indicated that such reliance on incorporation by reference for support is acceptable, provided that the Applicant clearly indicates the support in the references.

It is noted that although the Applicant believes that the US patent references describe some various ones of the recited claim limitations, the references do not teach or suggest, separately or in combination, the entirety of the invention claimed in any of the claims. In particular, the Applicant does not believe that any prior art reference describes apparatus that induces unidirectional orthodromic action potentials in non-contiguous periods.

Claim(s)	Support
73	US Patent 4,867,164 to Zabara, which is incorporated by reference in the specification as filed, states: "Although the sensing of electroencephalographic waves has been used above as an example for automatically turning on the neurocybernetic prosthesis, it should be apparent that other state parameters can be measured to provide a sensor-feedback system. Such other parameters might include respiration changes, heart rate changes, various auras or motor effects such as tics or myoclonic jerks" (col. 6, lines 55-62).
74	US Patent 5,540,730 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "SUMMARY OF THE INVENTION - The present invention takes advantage of the role of the vagus nerve in the digestive process, and its effect upon motility through the GI tract, but does so as a response to sensing abnormal motility characterized by hypomotility or hypermotility. An implanted device is used for nerve stimulation, and in one embodiment is implemented for automatic activation upon sensing a prescribed event indicative of a need for treatment, such as by sensing a particular pattern of contractions at a

	designated point along the GI tract. In an alternative embodiment, the implanted device is timed for automatic activation (for example, coinciding with each mealtime of the patient, or delayed to approximate the start of the digestive process in the stomach) to stimulate and electrically modulate the electrical activity of the vagus nerve to treat the disorder. In another alternative embodiment, the implanted device is configured to allow manual activation by the patient" (col. 3, line 54 – col. 4, line 4).
75	US Patent 5,335,657 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "...the disorder under treatment is insomnia, and including: detecting the physiological event by sensing a respiration pattern of the patient indicative of wakefulness during normal nocturnal hours..." (claim 7). "...the step of detecting the event is performed by sensing abdominal impedance changes associated with respiration by the patient indicative of the sleep disorder under treatment..." (claim 12). "A device for treating sleep disorders in human patients, ... said sensing means includes means for detecting a sustained abnormal period of cessation of respiration of the patient" (claims 19 and 23). "...the step of sensing is performed to detect respiration typically associated with a state of sleeplessness of the patient, during normal nocturnal hours" (claim 14). "The method and apparatus includes several techniques for detecting the presence of the sleep disorder under treatment, such as sensing the patient's EEG activity..." (abstract). "...the detected event includes one of ... (ii) a sudden uncontrolled nodding of the patient's head" (claim 9). "...said sensing means includes an abdominal impedance detector..." (claim 27). "...eye movement sensors may be implanted to detect REM or NREM sleep..." (col. 8, lines 23-24).

76	US Patent 5,263,480 to Wernicke et al., which is incorporated by reference in the specification as filed, states: "In the case of treating compulsive overeating and obesity, for example, it is desirable to ascertain the patient's food intake, i.e., the quantity consumed. To that end, sensing electrodes may be implanted in or at the esophagus to detect passage of food as the patient swallows" (col. 5, lines 53-58).
77	US Patent 5,188,104 to Wernicke, which is incorporated by reference in the specification as filed, states: "Apparatus for treating patients with eating disorders by application of a modulating signal to the patient's vagus nerve to stimulate or inhibit neural impulses and produce excitatory or inhibitory neurotransmitter release by the nerve according to the specific nature of the eating disorder, comprising: . . . sensing means for detecting the occurrence of a selected event indicative of the need for imminent treatment of the eating disorder, . . . said sensing means comprises means for detecting the consumption of food by the patient within a predetermined interval of time" (claims 8 and 13).
78	US Patent 5,188,104 to Wernicke, which is incorporated by reference in the specification as filed, states: "Alternatively, or in addition to the sensing electrodes 12 on the patient's esophagus, a set of bipolar electrodes 67 secured to the outer wall of the patient's stomach 13 (one at each of opposite sides as depicted in FIG. 3) may be utilized for purposes of measuring the amount of food in the stomach" (col. 11, lines 1-6).
79	US Patent 5,571,150 to Wernicke et al., which is incorporated by reference in the specification as filed, states: "FIG. 3 is a simplified fragmentary illustration of a lead/electrode system of a neurostimulator fully implanted in the patient's body for stimulating the vagus nerve, and with external electrodes for monitoring the patient's EEG" (col. 3, lines 1-4).

80	US Patent 5,707,400 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "A method of treating patients suffering from refractory hypertension includes identifying a patient suffering from the disorder and applying a stimulating electrical signal to the patient's vagus nerve predetermined to modulate the electrical activity of the nerve and to alleviate the hypertension. The step of applying the stimulation may be performed manually by the patient, or automatically following detection of the hypertension by sensing the patient's blood pressure. . ." (abstract).
81	"Driving the current typically, but not necessarily, includes driving the current into a vagus nerve of the subject" (p. 14, first paragraph, of the specification of the present application).
82	"US Patent 5,215,086 to Terry et al., which is incorporated herein by reference, describes a method for applying electrical stimulation to treat migraine headaches" (p. 4 of the specification of present application).
83	"US Patent 5,299,569 to Wernicke et al., which is incorporated herein by reference, describes a method for treating and controlling neuropsychiatric disorders, including schizophrenia, depression and borderline personality disorder, by selectively applying a predetermined electrical signal to the patient's vagus nerve, in order to alleviate the symptoms of the disorder being treated" (p. 3 of the specification of present application).
84 and 85	US Patent 4,702,254 to Zabara, which is incorporated by reference in the specification as filed, states: "Preferably, during a treatment period, the prosthesis may be activated once every hour or so for a minute or more with the frequency and duration gradually reduced to nothing at the end of the period which may be several hours or a week or more. Such

	treatment can eliminate seizures or at least reduce their frequency and intensity. This continuous cycling on and off is also most useful for treating continuous or chronic tremors such as Parkinsonism" (col. 5, lines 2-10).
86	US Patent 4,602,624 to Naples et al., which is incorporated by reference in the specification as filed, states: "Functional electrical stimulation of the nervous system has been shown in recent years to offer great hope in restoring some degree of lost sensory and motor function in stroke victims and individuals with spinal cord lesions" (col. 1, lines 15-19).

Claims 87-110 are new. These claims recite elements or combinations of elements recited in other claims as originally filed, or as amended with support as described herein, as shown in the following table. The Applicant believes these claims are allowable for the reasons discussed during the interview with Mr. Colb, as described hereinabove.

Claim	Elements from claim(s)	Claim	Elements from claim(s)
87	35 and 69	99	54
88	36	100	56-57
89	38	101	60
90	37	102	73
91	38	103	74
92	39	104	75
93	41	105	76
94	42	106	77
95	43	107	78
96	40 and 45-52	108	80

97	84 and 85	109	64
98	53	110	65

Independent claim 111 is new, and is supported in the specification as filed as discussed immediately hereinbelow. The Applicant notes that information that is incorporated by reference should be treated as part of the text of the application as filed, as discussed above. As mentioned above, during the interview with Mr. Colb, the Examiner indicated that such reliance on incorporation by reference for support is acceptable, provided that the Applicant clearly indicates the support in the references. It is noted that although the Applicant believes that the following articles describe some various ones of the recited claim limitations, the references do not teach or suggest, separately or in combination, the entirety of the invention claimed in any of the claims.

Support for inducing orthodromic action potentials and suppressing antidromic action potentials has already been provided in a response filed August 12, 2003 in the parent application (Application No. 09/944,913). Support for inducing action potentials in a first set of fibers, while substantially not inducing action potentials in a second set of fibers having diameters generally different from diameters of the first set, is provided in at least four articles incorporated by reference in the specification as originally filed:

Reference	Support
Fitzpatrick DM et al., "A nerve cuff design for the selective activation and blocking of myelinated nerve fibers," Ann. Conf. of the IEEE Eng. in Medicine and Biology Soc. 13(2):906-907 (1991)	"The results show that a tripolar cuff electrode can generate unidirectional action potentials in the small nerve fibres whilst blocking the large fibres. Changing the ratio of the anodal currents results in the gradual recruitment of the large fibres" (p. 907).
Rijkhof NJM et al., "Acute animal studies on the use of anodal block to reduce urethral resistance in sacral	"Our research is focused on selective activation of small nerve fibers in sacral roots by a combination of cathodal excitation of all

<p>root stimulation," IEEE Transactions on Rehabilitation Engineering 2(2):92-99 (1994)</p>	<p>fibers and a selective anodal block [1], [6]-[8] of the large fibers. . . . Since large diameter fibers need less current for their blocking than small ones [1], selective activation of small fibers is possible by blocking, distal to the excitation site (cathode), the propagation of the induced action potentials in the large fibers" (p. 92).</p>
<p>Rijkhoff NJM et al., "Orderly recruitment of motoneurons in an acute rabbit model," Ann. Conf. of the IEEE Eng., Medicine and Biology Soc. 20(5):2564-2565 (1998)</p>	<p>"At least 3 different methods are known that allow for selective small fiber activation, selective anodal blocking, high frequency stimulation and slowly rising pulses [2]. A project has been started to compare these 3 different methods with respect to performance, stability, required electrical charge per pulse. This abstract reports on the results obtained with only one of these methods, the selective anodal block [3]" (p. 2564).</p>
<p>Bratta R et al., "Orderly Stimulation of Skeletal Muscle Motor Units with Tripolar Nerve Cuff Electrode," IEEE Transactions on Biomedical Engineering 36(8):836-843 (1989)</p>	<p>"An electrical nerve stimulation technique, using single tripolar electrode, was shown to be capable of recruiting motor units according to their size, while allowing simultaneous but independent control of firing rate in the active units" (abstract).</p>

As shown in the following table, claims 112-120 are generally parallel to a subset of the claims of the issued parent application (US Patent 6,684,105) which depend from claim 1 thereof, with changes made to conform to independent claim 111:

Claim in present application	Parallel claim(s) in parent application
112	2
113	3
114	4
115	6, 11, 12, 13, 14, 15, 16, 17, and 18
116	21
117	35
118	24
119	25

Claim 120 is supported as described hereinabove with respect to claims 82-86.

Claim 111 is narrower than claim 1 of the parent application, as allowed and issued (as US Patent 6,684,105). The Applicant thus submits that claim 111 is in a condition for allowance. Claims 112-120 directly or indirectly depend from claim 111, and are thus also allowable, being of narrower scope than the allowable independent claim from which they depend.

Independent claim 121 is new. This claim recites a combination of elements of the allowed and issued claims of the parent application. Specifically, claim 121 includes the elements of independent claim 1 of the parent application, and dependent claims 4 and 35, both of which depend directly from claim 1.

As shown in the following table, claims 122-125 are generally parallel to a subset of the claims of the issued parent application which depend from claim 1 thereof, with changes made to conform to independent claim 121:

Claim in present application	Parallel claim(s) in parent application
122	2

123	3
124	6, 11, 12, 13, 14, 15, 16, 17, and 18
125	21

Claims 126-134 are new, and depend from claim 121. These claims are supported in the specification as filed at least as shown in the following table. The Applicant notes that information that is incorporated by reference should be treated as part of the text of the application as filed, as discussed hereinabove. As mentioned above, during the interview with Mr. Colb, the Examiner indicated that such reliance on incorporation by reference for support is acceptable, provided that the Applicant clearly indicates the support in the references.

It is noted that although the Applicant believes that the US patent references describe some various ones of the recited claim limitations, the references do not teach or suggest, separately or in combination, the entirety of the invention claimed in any of the claims.

Claim	Support
126	<p>US Patent 4,702,254 to Zabara, which is incorporated by reference in the specification as filed, states: "Preferably, during a treatment period, the prosthesis may be activated once every hour or so for a minute or more with the frequency and duration gradually reduced to nothing at the end of the period which may be several hours or a week or more. Such treatment can eliminate seizures or at least reduce their frequency and intensity. This continuous cycling on and off is also most useful for treating continuous or chronic tremors such as Parkinsonism" (col. 5, lines 2-10).</p> <p>"US Patent 5,215,086 to Terry et al., which is incorporated herein by reference, describes a method for applying electrical stimulation to treat migraine headaches" (p. 4 of the specification of present application).</p>
127	<p>US Patent 4,867,164 to Zabara, which is incorporated by reference in the specification as filed, states: "Although the sensing of</p>

	electroencephalographic waves has been used above as an example for automatically turning on the neurocybernetic prosthesis, it should be apparent that other state parameters can be measured to provide a sensor-feedback system. Such other parameters might include respiration changes, heart rate changes, various auras or motor effects such as tics or myoclonic jerks" (col. 6, lines 55-62).
128	US Patent 5,540,730 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "SUMMARY OF THE INVENTION - The present invention takes advantage of the role of the vagus nerve in the digestive process, and its effect upon motility through the GI tract, but does so as a response to sensing abnormal motility characterized by hypomotility or hypermotility. An implanted device is used for nerve stimulation, and in one embodiment is implemented for automatic activation upon sensing a prescribed event indicative of a need for treatment, such as by sensing a particular pattern of contractions at a designated point along the GI tract. In an alternative embodiment, the implanted device is timed for automatic activation (for example, coinciding with each mealtime of the patient, or delayed to approximate the start of the digestive process in the stomach) to stimulate and electrically modulate the electrical activity of the vagus nerve to treat the disorder. In another alternative embodiment, the implanted device is configured to allow manual activation by the patient" (col. 3, line 54 – col. 4, line 4).
129	US Patent 5,335,657 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "... the disorder under treatment is insomnia, and including: detecting the physiological event by sensing a respiration pattern of the patient indicative of wakefulness during normal nocturnal hours..." (claim 7). "... the step of detecting the event is performed by sensing abdominal impedance changes associated with

	<p>respiration by the patient indicative of the sleep disorder under treatment. . ." (claim 12). "A device for treating sleep disorders in human patients, . . . said sensing means includes means for detecting a sustained abnormal period of cessation of respiration of the patient" (claims 19 and 23). ". . . the step of sensing is performed to detect respiration typically associated with a state of sleeplessness of the patient, during normal nocturnal hours" (claim 14). "The method and apparatus includes several techniques for detecting the presence of the sleep disorder under treatment, such as sensing the patient's EEG activity. . ." (abstract). ". . . the detected event includes one of . . . (ii) a sudden uncontrolled nodding of the patient's head" (claim 9). ". . . said sensing means includes an abdominal impedance detector. . ." (claim 27). ". . . eye movement sensors may be implanted to detect REM or NREM sleep. . ." (col. 8, lines 23-24).</p>
130	<p>US Patent 5,263,480 to Wernicke et al., which is incorporated by reference in the specification as filed, states: "In the case of treating compulsive overeating and obesity, for example, it is desirable to ascertain the patient's food intake, i.e., the quantity consumed. To that end, sensing electrodes may be implanted in or at the esophagus to detect passage of food as the patient swallows" (col. 5, lines 53-58).</p>
131	<p>US Patent 5,188,104 to Wernicke, which is incorporated by reference in the specification as filed, states: "Apparatus for treating patients with eating disorders by application of a modulating signal to the patient's vagus nerve to stimulate or inhibit neural impulses and produce excitatory or inhibitory neurotransmitter release by the nerve according to the specific nature of the eating disorder, comprising: . . . sensing means for detecting the occurrence of a selected event indicative of the need for imminent treatment of the eating disorder, . . . said sensing means comprises means for detecting the consumption of food by the patient within a predetermined interval of</p>

	time" (claims 8 and 13).
132	US Patent 5,188,104 to Wernicke, which is incorporated by reference in the specification as filed, states: "Alternatively, or in addition to the sensing electrodes 12 on the patient's esophagus, a set of bipolar electrodes 67 secured to the outer wall of the patient's stomach 13 (one at each of opposite sides as depicted in FIG. 3) may be utilized for purposes of measuring the amount of food in the stomach" (col. 11, lines 1-6).
133	US Patent 5,571,150 to Wernicke et al, which is incorporated by reference in the specification as filed, states: "FIG. 3 is a simplified fragmentary illustration of a lead/electrode system of a neurostimulator fully implanted in the patient's body for stimulating the vagus nerve, and with external electrodes for monitoring the patient's EEG" (col. 3, lines 1-4).
134	US Patent 5,707,400 to Terry, Jr. et al., which is incorporated by reference in the specification as filed, states: "A method of treating patients suffering from refractory hypertension includes identifying a patient suffering from the disorder and applying a stimulating electrical signal to the patient's vagus nerve predetermined to modulate the electrical activity of the nerve and to alleviate the hypertension. The step of applying the stimulation may be performed manually by the patient, or automatically following detection of the hypertension by sensing the patient's blood pressure. . ." (abstract).

Claim 121 is narrower than claim 1 of the parent application, as allowed and issued (as US Patent 6,684,105). The Applicant thus submits that claim 121 is in a condition for allowance. Claims 122-134 directly or indirectly depend from claim 121, and are thus also allowable, being of narrower scope than the allowable independent claim from which they depend.

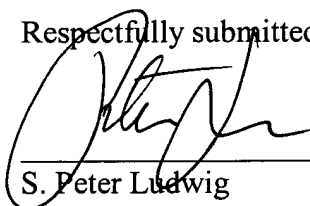
The Applicant brings to the Examiner's attention copending Application Nos. 10/488,334 (filed July 6, 2004), 10/529,149 (filed October 24, 2005), 10/719,659 (filed November 20, 2003), 10/948,516 (filed September 23, 2004), 11/022,011 (filed December 22, 2004), 11/070,842 (filed February 21, 2005), 11/234,877 (filed September 22, 2005), 11/280,884 (filed November 15,

2005), and 11/347,120 (filed February 2, 2006), and co-assigned US Patent 6,907,295, issued June 14, 2005, which may be material to patentability of the present application.

The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Date: October 4, 2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Peter Ludwig', is written over a horizontal line.

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